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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,752	09/09/2003	Kenneth Stephen Albert	54203US	1173

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,752	ALBERT ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) *7,8,71-73,75,76,79 and 81-116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-70,74,77,78 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election Requirement and Applicant's Arguments/Remarks, all filed 11/01/06 is acknowledged.

Applicant's election with traverse of (1) method of treating; (2) microgranules and (3) myocardial ischemia in the reply filed on 11/01/06 is acknowledged. The traversal is on the ground(s) that "(1) It would not constitute an undue burden on the Office to examine a method of treating myocardial ischemia and angina with a method of preventing myocardial ischemia and angina; (2) It would not constitute an undue burden on the Office to examine a method of treating and preventing myocardial ischemia with any of the dosage forms listed in the Office Action; and (3) It would not constitute an undue burden on the Office to examine a method of treating and preventing myocardial ischemia with a method of treating and preventing angina because, *inter alia*, angina is known to be a symptom of myocardial ischemia". This is not found persuasive because no declaration of equivalency has been established between the various forms (tablets, capsules, microgranules, etc.) claimed. A search of the prior art for each of the above-identified forms has different rates of release and required different procedures for formulation. Hence, they are capable of supporting a separate patent within the art. The undue burden identified by the art is based on the various diverse classifications, i.e., 424/451 & 456 – capsules; 424/464 – tablets; and 424/489 – particles, granules, etc.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 8, 71-73, 75, 76, 79 and 81-116 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/01/06.

Claims 1-116 are pending in this action. Claims 5-15, 17, 18, 55-57, 71, 77, 79 and 81-116 have been amended. Claims 7, 8, 71-73, 75, 76, 79 and 81-116 have been withdrawn. Claims 1-6, 9-70, 74, 77, 78 and 80 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-70, 74, 77, 78 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite "a method of treating or preventing myocardial ischemia...". The term "preventing" renders the claims non-enabling. It is suggested that the term "preventing" be deleted for each applicable claim to overcome this rejection.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation

(1) The nature of the invention/(5) The breadth of the claims:

The invention is directed to a method of treating or preventing myocardial ischemia and angina in a patient comprising administering a controlled-release galenical preparation of pharmaceutically acceptable form of Diltiazem, including pharmaceutically acceptable salts thereof for evening dosing every 24 hours.

(2) The state of the prior art:

The prior art teachings provide for formulations of sustained- or slow-release of diltiazem, which is used for its activity in treating angina. The formulations can be administered twice a day. The compositions can be in various forms, which include capsules, pills or sachets containing microgranules (see for instance column 1, line 40 – col. 2, line 7 of Debregeas *et al.* – U.S. Patent No. 4,960,596).

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The unpredictability of the art is high.

(6) The amount of direction or guidance presented:

The specification filed 09/09/03 discloses 'treatment or prevention' of myocardial ischemia and angina in patients (see pg. 1, lines 8-10 of specification). While similar prior art formulations recognize compositions for treating myocardial ischemia and/or angina comprising administration of diltiazem in sustained release preparations, the prior art does not recognize "prevention" of myocardial ischemia and/or angina. It is unclear to the Examiner as to how the instant composition 'prevents' myocardial ischemia and/or angina, whilst prior art formulations, which incorporate the same components as claimed by Applicant, only provide for the 'treatment' of myocardial ischemia and/or angina. The specification while providing guidance for the 'treatment' of myocardial ischemia and/or angina does not provide any direction or guidance for the 'prevention' of myocardial ischemia and/or angina.

(7) The presence or absence of working examples:

The working examples are insufficient to establish the instant "prevention" of myocardial ischemia and angina. The working examples merely establish that the instant compositions can be used to alleviate or treat myocardial ischemia and angina, but not prevent them. Therefore, the working examples are insufficient to establish the instant composition used to 'prevent' myocardial ischemia and angina.

(8) The quantity of experimentation necessary:

The instant invention provides for a method of treating or preventing myocardial ischemia and angina in a patient comprising administering a controlled-release galenical preparation of pharmaceutically acceptable form of Diltiazem, including pharmaceutically acceptable salts thereof for evening dosing every 24 hours. When the above factors are weighed together, it is the position of the Examiner that the instant invention would require 'undue' and painstaking experimentation to arrive at the instant invention to determine how to effectively treat myocardial ischemia and angina, with the "*prevention*" of myocardial ischemia and angina being even less probable.

Pertinent Art

Prior Art made of record, not relied upon, and deemed relevant by Examiner:

- Chen *et al.* – U.S. Pat. No. 6,524,620:

  Chen *et al.* teach a controlled release diltiazem dosage formulation comprising a plurality of active pellets coated with an extended release coating wherein the active pellets comprise diltiazem or a pharmaceutically acceptable salt (see Abstract).

- Philippon *et al.* – U.S. Pat. No. 5,229,135 :

  Philippon *et al.* teach a sustained release diltiazem formulation suitable for once daily oral administration (see column 2, lines 9-24).

- Desmolin – U.S. Pat. No. 5,344,657:

  Desmolin teaches sustained-release diltiazem formulations comprising microbeads. They can be administered orally once or twice per day for the treatment of angina or hypertension (see Abstract).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner

Art Unit 1615

January 06, 2007

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